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EXAMINER	
SHAW, AMANDA MARIE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,522	NAKAMURA ET AL.	
	Examiner	Art Unit	
	AMANDA SHAW	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Prior to setting forth this restriction requirement it is noted that claim 29 recites "the method for inducing anti tumor immunity of claim 27, wherein the method further comprises", however claim 27 is drawn to "a method of treating or preventing breast cancer". Therefore it appears that claim 29 should actually depend from claim 28 which is drawn to "a method for inducing anti-tumor immunity.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6 (in part) and 7, drawn to a method of diagnosing breast cancer or a predisposition to breast cancer using nucleic acid analysis, classified in class 435, subclass 6.

II. Claims 6 (in part), drawn to a method of diagnosing breast cancer or a predisposition to breast cancer using protein analysis, classified in class 435, subclass 7.1.

III. Claims 12-21, drawn to a method of screening for a compound for treating or preventing breast cancer, classified in class 424, subclass 9.1.

IV. Claim 22 (in part), drawn to a kit comprising detection reagents for nucleic acid analysis, classified in class 536, subclass 24.1.

V. Claim 22 (in part), drawn to a kit comprising detection reagents for protein analysis, classified in class 514, subclass 2.

VI. Claims 23-25, 30-33, 36, and 40 drawn to a method for treating or preventing breast cancer in a subject by administering an antisense or siRNA composition, classified in class 514, subclass 44.

VII. Claims 26, 30, 34, 36, and 40, drawn to a method for treating or preventing breast cancer in a subject by administering an antibody or immunologically active fragment thereof, classified in class 424, subclass 130.1.

VIII. Claims 27-29, 30, 35-36, and 40, drawn to a method for treating or preventing breast cancer in a subject by administering a vaccine comprising a polypeptide, classified in class 514, subclass 12.

IX. Claims 37-39, and 41-44, drawn to a composition for treating or preventing breast cancer comprising an antisense or siRNA nucleotide, classified in class 536, subclass 24.51.

X. Claims 39 and 43-44 drawn to a composition for treating or preventing breast cancer comprising an antibody, classified in class 424, subclass 130.1.

Linking Claims

3. Claims 1-5 and 8-11 link the inventions of groups I and II set fourth above. The restriction requirement between the linked combinations and subcombinations is **subject to** the nonallowance of the linking claim(s). Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be

withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-III and VI-VIII are related as distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Inventions I-II are drawn to methods of diagnosing breast cancer, Invention III is drawn to a method of screening a compound for treating breast cancer and Inventions

VI-VIII are drawn to methods for treating breast cancer, and thus they have different modes of operation and effects, since the conclusion drawn for each method versus the other is different. Further Inventions I-II are distinct from each other because one method requires nucleic acid analysis while the other requires amino acid analysis. Additionally Inventions VI-VIII are distinct from each other because one method requires treatment with antisense or siRNA, one method requires treatment with an antibody, and the third method requires treatment with a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Invention IV can be used in materially different processes such as synthesizing nucleic acids or amino acids or for therapeutic methods.

Inventions I and V and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention V, the antisense RNA of Invention IX and the antibodies of Invention X are not required to detect the RNA of

Invention I. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions II and III and VI-VIII are related as distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Invention II is drawn to methods of diagnosing breast cancer, Invention III is drawn to a method of screening a compound for treating breast cancer and Inventions VI-VIII are drawn to methods for treating breast cancer, and thus they have different modes of operation and effects, since the conclusion drawn for each method versus the other is different. Further Inventions VI-VIII are distinct from each other because one method requires treatment with antisense or siRNA, one method requires treatment with an antibody, and the third method requires treatment with a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides

of Invention V can be used in materially different processes such as for therapeutic methods.

Inventions II and IV and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Invention IV, the antisense RNA of Invention IX and the antibodies of Invention X are not required to detect the proteins of Invention II. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions III and VI-VIII are related as distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Invention III is drawn to a method of screening a compound for treating breast cancer and Inventions VI-VIII are drawn to methods for treating breast cancer, and thus they have different modes of operation and effects, since the conclusion drawn for each method versus the other is different. Further Inventions VI-VIII are distinct from each other because one method requires treatment with antisense or siRNA, one method requires treatment with an antibody, and the third method requires treatment with a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention V can be used in materially different processes such as for therapeutic methods.

Inventions III and IV and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Invention IV, the antisense RNA of Invention IX and the antibodies of Invention X are not required to detect the proteins of Invention II. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions IV and V and IX-X are directed to distinct products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are patentably distinct in structure and physiochemical properties. Invention IV is drawn to polynucleotides, Invention V is drawn to polypeptides, Invention IX is drawn to antisense and/or siRNA, and Invention X is drawn

to antibodies. Polynucleotides are composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. Polypeptides are composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops. Although antibodies are also composed of amino acids, the antibodies have distinct structural limitations and particular immunological functions that distinguish them from other polypeptides. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, the proteins may be utilized in ligand binding assays, antisense may be used to prevent expression and the antibodies may be used therapeutically. Consequently, the reagents, reactions conditions, and reaction parameters to made or use each invention are different. Therefore the inventions are patentably distinct from each other.

Inventions IV and VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Invention IV are not required by the methods of Inventions VI-VIII. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions V and IX-X are directed to distinct products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as

claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are patentably distinct in structure and physiochemical properties. Invention V is drawn to polypeptides, Invention IX is drawn to antisense and/or siRNA, and Invention X is drawn to antibodies. Polynucleotides are composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. Polypeptides are composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops. Although antibodies are also composed of amino acids, the antibodies have distinct structural limitations and particular immunological functions that distinguish them from other polypeptides. Furthermore, the products are utilized in different methodologies, such that proteins may be utilized in ligand binding assays, antisense may be used to prevent expression and the antibodies may be used therapeutically. Consequently, the reagents, reactions conditions, and reaction parameters to made or use each invention are different. Therefore the inventions are patentably distinct from each other.

Inventions V and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention V are not required by the methods of Inventions VI-VII. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention V can be used in materially different processes such as for binding assays.

Inventions VI and VII-VIII are related as distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Inventions VI-VIII are drawn to methods for treating breast cancer. Inventions VI-VIII are distinct from each other because one method requires treatment with antisense or siRNA, one method requires treatment with an antibody, and the third method requires treatment with a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antisense

molecules of Invention VI can be used in materially different processes such as for binding assays.

Inventions VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Invention X are not required by the methods of Inventions VI. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions VII and VIII are related as distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Inventions VI-VIII are drawn to methods for treating breast cancer. Inventions VI-VIII are distinct from each other because one method requires treatment with an antibody, and the other method requires treatment with a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antisense molecules of Invention IX are not required by the method

of Invention VII. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in materially different processes such as for binding assays.

Inventions VIII and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antisense molecules of Invention IX and the antibodies of Invention X are not required by the method of Invention VIII. Further they have different designs, modes of operation and effects since one invention is a product and one is a method.

Inventions IX-X are directed to distinct products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are patentably distinct in structure and physiochemical properties. Invention IX is drawn to antisense and/or siRNA and Invention X is drawn to antibodies.

Polynucleotides are composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. Antibodies are composed of amino acids and have distinct structural limitations and particular immunological functions that distinguish them from other polypeptides. Furthermore, the products are utilized in different methodologies, such that proteins may be utilized in ligand binding assays, antisense may be used to prevent expression and the antibodies may be used therapeutically. Consequently, the reagents, reactions conditions, and reaction parameters to made or use each invention are different. Therefore the inventions are patentably distinct from each other.

Additional Election Requirement Applicable to all Inventions

5. The claims are drawn to methods and compositions some of which require a single gene product (i.e. protein or nucleic acid) and some of which require multiple gene products. The language "one of more" (clm 13) requires one, two, or three genes. For example, a method of contacting a candidate compound with a cell expressing A5657 is distinct from a method of contacting a candidate compound with a cell expressing B9769 because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). In the instant case each gene and the various combinations thereof also encompassed by the claims, differ in sequence and structure from one another, and possess different functional properties and characteristics.

The claims further encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of "one or more" gene as disclosed in claim 13.

Subcombination (A): the A5657 gene

Subcombination (B): the B9769 gene

Combination (A+B): the A5657 and B9769 genes

Each of the combinations of genes is related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in scope and there is no evidence on the record to suggest that they are obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as for making proteins. So, subcombinations (A) and (B) are distinct. See MPEP § 806.05(d).

These subcombinations are also distinct from the combination which comprises them because the combination does not require the particulars of the subcombination as claimed to show novelty or unobviousness and the subcombinations have utility by themselves or in another combination. The fact that the claim encompasses an embodiment which relies on only subcombination (B) is evidence that the details of subcombination (A) are not required for patentability of the combination (A+B), and likewise, the fact that the claim encompasses an embodiment which relies on only subcombination (A) is evidence that the details of subcombination (B) are not required for patentability of subcombination (A+B). The fact that the claim encompasses embodiments which use only subcombination (A) or subcombination (B) is evidence that the subcombinations have utility by themselves.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Each gene must be searched by a separate query of the electronic databases. See MPEP 808.02(C). Therefore, a search for methods which use each gene or each combination of genes is not co-extensive, and subsequently, the search and examination for every gene and every combination of genes poses an enormous and serious burden on the examiner.

For groups I, II, VI-XI the Applicant is required to select a single invention, i.e., a single gene.

For groups III-V Applicant is required to select a single invention, i.e., a single gene or a single combination of genes. The invention may be a single gene, a combination of more than one gene but less than all of the disclosed genes or a combination of all possible claimed genes. However, an election of a single invention, i.e., a single gene or a single combination of genes is required. This restriction requirement is predicated on the fact that the methods which use different genes or different combinations of genes do not appear obvious over one another. Should applicant traverse on the ground that the different genes or different combinations of

genes are not patentably distinct over each other , applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variant over each other or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant is also required to identify which claims read upon the elected invention.

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Sequence Election Requirement Applicable to Inventions VI and X

6. The claims of Invention VI and X encompass distinct nucleic acid sequences. Specifically claims 25 and 38 recite one oligonucleotide selected from the group consisting of SEQ ID NOs 28-34. Specifically claims 33 and 42 encompass one oligonucleotide selected from the group consisting of SEQ ID NOs 28-29. A search of

the claims would require at least 7 separate sequence searches and consideration of any prior art relevant to each sequence searched. The 7 different nucleic acid sequences encompassed by the claims, differ in sequence and structure from one another, and possess different functional properties and characteristics. In accordance with the policy set forth in 1316 OG 122 (27 March 2007), claims directed to polynucleotide molecules are considered for independence, relatedness, distinction, and burden as for claims to any other type of molecule. In the instant case, the nucleic acid sequences each constitute a distinct invention. Further as each sequence would require a different sequence search, a search of more than one such sequence would pose a serious burden on the examiner and on the Office.

Accordingly, the oligonucleotides are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, applicant should elect a single sequence selected from the group consisting of SEQ ID NOs: 28-34.

7. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Juliet C Switzer/
Primary Examiner, Art Unit 1634